REMARKS

Reconsideration is respectfully requested. Claims 1- 29 , and 31-37 are pending. Claims 1 -13, 15-17, 19-29, and 31-37 have been amended. Claim 30 has been canceled. Claims 14-18 have been withdrawn. No new matter has been added due to the amendments. Amendments to the claims do not affect inventorship.

Applicant has not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Amendments

Claims 1 -13, 15-17, 19-29, and 31-37 have been amended for technical clarity.

Claim Objections

Claims 2-13 and 20-37 are objected to because of the informalities.

Claim 30 has been canceled, rendering the objection moot.

Claim 2-13 and 2-37 have been amended to correct the informality. As such, Applicant respectfully requests the amendments be entered and the objections be withdrawn.

Applicant notes that these amendments are in response to objections, not rejections, and by definition are not made for reason related to patentability under Title 35 of the United States Code.

Claim Rejection under 35 U.S.C. § 101

Statutory subject matter rejection

Claims 1-13 and 19-37 stand rejected under 35 U.S.C. § 101 on the basis that the claimed invention is directed to non-statutory subject matter. Applicant respectfully traverses.

Claim 1-13, and 20-37

To satisfy section 101 requirements, a method may be statutory where it recites a concrete, tangible and useful result. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (USPTO, 2005) ("Guidelines") at 19.

Claims 2-13, and 20-37 depend from claim 1, which as amended recites: "communicating said first or second hypothetical model that best represents the system to a user in a tangible form."

Because the result is an output that is communicated to a user in a tangible form, the claimed result recite a result that is concrete, tangible and useful. As such the claims are statutory and Applicants respectfully request the rejections be withdrawn.

Claim 19

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. MPEP § 2106.

Claim 19, as amended, recites "[a] computer readable medium to direct a computer to function in a specified manner to derive and optimize a mathematical model for a system."

Applicant respectfully submits that claim 19 is directed to a patentable subject matter because it is directed to functional descriptive material (the modules) that is recorded on computer-readable medium. As such, claim 19 is directed to statutory subject matter and Applicant respectfully requests the rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 2-13 and 29 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. This is a new matter rejection. Applicant respectfully traverses.

Claim 3-13 and 29 depend from claim 2, which recite:

ii) a feasibility test against theoretical constraints of thermodynamic principles; and

iii) a feasibility test against theoretical constraints of physical laws.

The specification discloses in paragraph [069] that:

> [C]ertain enzymatic steps must be in certain orders: the enzymatic conversion of a substrate cannot come before its creation, etc. These "rules" are generally drawn from the literature or thermodynamic principles. "Constraints-based" modeling approaches, such as those described by ... can be incorporated in the fitness function.
>
> ....
>
> [T]he fitness function may include user-definable limiting assumptions, such as a test for multiplicity of steady-states or violation of physical and chemical laws (i.e. constraints).

Thus there is amble support for claim 2 in the instant application and Applicant respectfully requests the rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 4, 6-13, 26-28, and 30-37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 30 has been cancelled, rendering the rejection moot.

Claim 4 stand rejected for lack of clarity for using numbering similar to claim 1. Claim 4 has been amended to use different numbering. As such, Applicant respectfully requests the rejection on this basis be withdrawn.

Claim 4 stand rejected on the basis of insufficient antecedent basis. Claim 4 has been amended to recite "said first or second hypothetical mathematical that best represents the system." As such, Applicant respectfully requests the rejection on this basis be withdrawn.

Claim 6 stand rejected on the basis that the limitation "utilize a comparison" is vague and indefinite. Without acquiescing to the propriety of the rejection, Applicant has amended claim 6 to recite "said fitness function is a direct comparison." As such, Applicant respectfully requests the rejection on this basis be withdrawn.

Claims 26-28 stand rejected for insufficient antecedent basis of the limitations "mathematical model" or "said mathematical model." Claims 26-28 have been amended for clarification. As such, Applicant respectfully requests the rejection be withdrawn.

Claims 33 and 34 stand rejected for insufficient antecedent basis of the limitations "said first differential protein expression data." The claims have been amended to recite "said first differential protein expression data points." As such, Applicant respectfully requests the rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 102

Claims 1-7, 19-22, 27, and 29-30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laurikkala et al. (*Computer Meths. Prog. Biomed.* 55:217-228 (1998) ("*Laurikkala*"). Applicant respectfully traverses.

Claim 30 has been cancelled, rendering the rejection moot.

For an anticipation rejection under 35 U.S.C. § 102 to be proper, a single reference must disclose each and every element of a claim. *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); M.P.E.P. § 2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The claimed invention is directed to method and apparatus "to derive and optimize a mathematical model for a system." Claim 2-7, 21, 22, 27, and 29 depend from claim 1, which recites "a plurality of unit operations." Claim 19 recites "a unit operations module." Claims 1 and 19 also recite "wherein said unit operation is a mathematical representation of a physical, chemical, or biological process, or kinetic expression."

In contrast, *Laurikkala* discloses a rules-based systems driven by empirical measurements. It is a general purpose learning system that uses a genetic algorithm to discover the rules for an expert system from a database. See Abstract. There is no mention in *Laurikkala* of any role for a mathematical representation of a system such as a differential equation or difference equation model.

Therefore, *Laurikkala* does not teach " a plurality of unit operations" as claim 1 recites, or "a unit operations module" as claim 19 recites.

Because *Laurikkala* does not teach each and every limitation of claim 1 and 19, it does not anticipate claims 1 and 19 and claims depend therefrom. Applicant respectfully requires the rejection on this basis be withdrawn.

Claim Rejection Under 35 U.S.C. § 103

Claims 8, 11-13, 23-26, 28, 31-32, and 34-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Laurikkala* in view of Addison (US 2004/0143725 A1) ("*Addison*"). Applicant respectfully traverses.

Claims 9-10, and 36-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Laurikkala* in view of *Addison* and further in view of Hood et al. (US 2002/0095259 A1) ("*Hood*"). Applicant respectfully traverses.

Claims 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Laurikkala* in view of *Addison* and further in view of Cubicciotti (US 2002/0034757 A1) ("*Cubicciotti*"). Applicant respectfully traverses.

When rejecting claims under 35 U.S.C. §103, the Examiner bears the burden of establishing a prima facie case of obviousness. See, e.g., *In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. Section 2142. To establish a *prima facie* case, the prior art reference(s) must teach or suggest each and every limitation of the rejected claims. *re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. §2142.

As discussed above, *Laurikkala* failed to teach the limitation "unit operation" and this defect is not cured by *Addison, Hood, or Cubicciotti.*

Addison is directed to a computer architecture called Whole Cell Compute, which is based on the biochemical processing of cells. See Abstract. It does not teach "unit operation."

Hood is directed to a method of determining a comparative expression profile in an individual by comparing the expression level of a sample of molecules in different populations. See Abstract. Nowhere does it teach "unit operation."

Cubicciotti is directed to single-molecule selection methods for identifying target-binding molecules. See Abstract. It does not teach "unit operation."

Because none of the references teaches "unit operation", they do not teach each and every limitation of the claimed invention. As such, the Examiner fails to make a *prima facie* case of obviousness and the rejections should be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 442-1000.

Respectfully submitted,
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